

Remarks/Arguments:

Claims 1-14 were pending. With this amendment, claims 1-14 have been cancelled, and claims 15-29 are new. Accordingly, claims 15-29 are now pending.

Claims 15-29 are supported throughout the original specification. For example, based on the supplemental substitute specification, new claim 15 is supported at page 1, lines 17-24; page 2, lines 19-21; and page 4, line 21 to page 5, line 3. New claim 16 is based on former claim 14. New claim 17 is based on former claim 1. New claim 18 is based on former claim 3. New claim 19 is based on former claim 4. New claim 20 is based on former claim 6. New claim 21 is based on former claim 7. New claim 22 is based on former claim 8. New claim 23 is based on former claim 9. New claim 24 is based on former claim 10. New claim 25 is based on former claim 11. New claim 26 is based on former claim 12. New claim 27 is supported at page 3, lines 22-25. New claim 28 is supported at page 4, line 26. New claim 29 is supported at page 5, line 2. No new matter has been added.

Oath or Declaration

The Office objected to the Oath or Declaration for failing to identify the application number and filing date. A new Declaration/Power of Attorney is submitted herewith.

Abstract

The Office objected to the abstract for using legal phraseology such as "comprises" and "said". The abstract has been amended herewith to correct this language. Accordingly, this objection is now moot.

Specification

Due to a minor typographical error in the translation, Applicant has amended the specification and claims to recite "recipient" instead of "receptor," which was used in the original German priority document. No new matter has been added.

Rejections under 35 U.S.C. §112

Claims 1-14 stand rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite. Claims 1-14 have been cancelled, and claims 15-29 are new. Applicant respectfully submits that the issues raised by the Office have been address in the new claims. Accordingly, the rejection is now moot.

Rejections under 35 U.S.C. § 102

Claims 1 and 6 stand rejected as anticipated by U.S. Patent No. 4,055,394 (Friedman). Claims 1-2 and 6-9 stand rejected as anticipated by U.S. Patent No. 4,851,210 (Hewett). Applicant respectfully traverses these rejections and submits that the currently pending claims are patentable over the cited references for at least the reasons set forth below.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P. §2131 *citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

New claim 15 recites:

A method for testing blood during the preparation and performance of **bedside-tests**, wherein the method comprises:
first, testing blood from a blood bag by using a first test unit of a test element;
subsequently, fixing the test element at the blood bag; and
thereafter, testing blood from a recipient by using a second test unit of the test element.

Rejections over Friedman

Friedman fails to disclose the method as claimed. In particular, Friedman fails to disclose first testing blood from a blood bag, then fixing the test element at the blood bag, and then testing blood from a recipient using the same test element. Friedman discloses a foldable test card where an AB0 test for a donor may be carried out and conserved. The test card is coated with an adhesive layer such that when the test is completed, the device is closed. Friedman also notes that the card may be affixed to a donor history card 40. See also column 4, lines 49-52 and Figures 3 and 4. There is no teaching of testing blood from a blood bag, however. Moreover, Friedman's device only allows for a single blood test. Test

surface 12 has two test circles 14 for anti-B antiserum and anti-A antiserum, but this is testing for a single blood sample. In other words, the test card of Friedman does not allow for the testing of both donor and recipient blood. Accordingly, there is no feasible way for the device of Friedman to carry out the claimed method of first testing blood from a blood bag, and then testing blood from a recipient using the same test element.

As Friedman fails to disclose or suggest each of the claim elements, claim 15 is not anticipated by Friedman. Claims 16-29 depend from claim 1, and therefore should each be allowed as dependent thereon.

Rejections over Hewett

Similarly, Hewett fails to disclose first testing blood from a blood bag, then fixing the test element at the blood bag, and then testing blood from a recipient using the same test element. Hewett describes a blood bag tag for use, e.g., in a blood bank. The tag includes testing regions for blood groups A, B, D, and control regions C+ (anti RCB) and C- (neutral polymer). See Figure 4. Donor blood from a bag is supplied to the testing regions. After an incubation period, the card is washed and dried. The card may be permanently attached, e.g., by stapling, clamping, etc., to the blood bag in a blood donor setting. In the case of a blood recipient, the card may be attached to the hospital record or a bracelet for the patient. Column 9, lines 9-27. Hewett does not provide for, however, testing of both the donor and recipient's blood. The device only allows for a single blood test. Test surface 20 has three tests for antibodies 23, 24, and 25 and two controls 21 and 22, but this is again testing for a single blood sample. Accordingly, there is no feasible way for the device of Hewett to carry out the claimed method of first testing blood from a blood bag, and then testing blood from a recipient using the same test element.

Therefore, Hewett also fails to disclose or suggest each of the claim elements, and claim 15 is not anticipated by Hewett. Claims 16-29 depend from claim 1, and therefore should each be allowed as dependent thereon.

Rejections under 35 U.S.C. § 103

Claims 3-5 stand rejected as obvious over Hewett. Claims 10-14 stand rejected as obvious over Hewett in view of EP 0,741,296 (Menu). Claims 1-14 stand rejected as obvious over Menu in view of Hewett. Applicant respectfully traverses these rejections and

submit that the currently pending claims are patentable over the cited references for at least the reasons set forth herein.

"To establish a *prima facie* case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §2143.

Rejections over Hewett

As discussed in detail above, Hewett fails to disclose or suggest the claimed method of first testing blood from a blood bag, then fixing the test element at the blood bag, and then testing blood from a recipient using the same test element. Therefore, a *prima facie* case of obviousness has not been established, and claims 15-29 should be deemed allowable.

Rejections over Hewett and Menu

For the reasons discussed above, Hewett fails to disclose the claimed method. Menu fails to remedy the deficiencies of Hewett. In particular, Menu also fails to disclose or suggest the claimed method of *first* testing blood from a blood bag, *then* fixing the test element at the blood bag, and *then* testing blood from a recipient. Menu discloses a foldable test card that can evaluate the compatibility of a donor with the blood of a recipient. Menu does not disclose, however, testing blood from a blood bag. Moreover, Menu does not disclose fixing the test element to a blood bag. Menu merely states the test may be preserved in the file of a patient. Additionally, Menu describes that each of the bins is intended to receive a drop of blood from the recipient and the donor, but there is no indication that the donor blood should be tested first and the recipient blood should be tested last. Thus, Menu fails to disclose the claimed method.

Moreover, even if the skilled person would have provided an adhesive layer on the back of the foldable test card of Menu, the card would have been applied to the patient's file. On the other hand, if the skilled person would have contemplated a second test area as disclosed by Menu, Hewett teaches that in the case of a recipient, the card shall be attached to the hospital record or a bracelet. Thus, the skilled person would have provided two separate test cards, one for the blood bag and one for the recipient, which would have resulted in the same problems, such as confusion, encountered by the prior art and still would not have arrived at the claimed invention. Therefore, the combination of Hewett and

Menu does not disclose a two-sided test card (for donor blood from a blood bag and recipient blood), which is adhered to a blood bag.

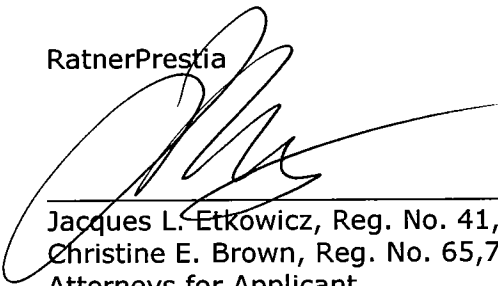
For the foregoing reasons, even in combining Hewett and Menu, the claimed sequence of *first* testing blood from a blood bag, *then* fixing the test element at the blood bag, and *then* testing blood from a recipient is not disclosed or suggested. Therefore, a *prima facie* case of obviousness has not been shown and claims 15-29 are in condition for allowance.

Conclusion

For all of the foregoing reasons, Applicant respectfully requests reconsideration and allowance of the claims. Applicant invites the examiner to contact their undersigned representative if it appears that this may expedite examination.

Respectfully submitted,

RatnerPrestia



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JLE/CEB/kpc

Attachment: Abstract

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authorized to charge payment to Deposit
Account No. **18-0350** of any fees associated
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